



Pharmaceutical Integrity

May 2013

Walgreens
AT THE CORNER OF **HAPPY & HEALTHY™**

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PLAINTIFFS TRIAL
EXHIBIT
P-14746_00001

Agenda

- Brief overview of Pharmaceutical Integrity
- Target Drug GFD Policy – General Information
- Updates
- Feedback/Questions



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Pharmaceutical Integrity

- Created to protect and grow Walgreens controlled substance business
- Transforming community pharmacy to play a greater role in the Opioid Narcotic Epidemic
- Managing, creating, and maintaining controlled substance dispensing, monitoring and reporting programs including the National Target Drug Good Faith Dispensing program



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Rx Integrity was created to protect and grow Walgreens controlled substance business while transforming community pharmacy to play a greater role in the Opioid Narcotic Epidemic and protect our business against high risk prescribers.

Rx Integrity is responsible for managing, creating, and maintaining controlled substance dispensing, monitoring and reporting programs including the Good Faith Dispensing Policy, and the National Good Faith Dispensing program.

Pharmaceutical Integrity

- Review orders that are manipulated by the store in order to determine whether the order meets specific criteria to qualify as suspicious. Suspicious orders are sent to the DEA and State Boards as required
- Work closely with various departments including Legal, Government Affairs, Logistics, Inventory, Loss Prevention, IT and others to ensure company wide awareness and adherence to federal, state, and local laws and regulations



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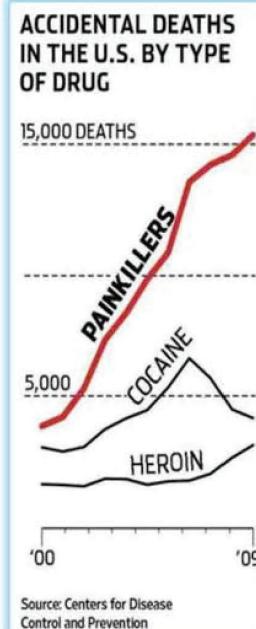
Rx Integrity team identifies and minimizes loss of Company assets and ensures the safety, compliance and security of the ordering and dispensing of controlled substances. The Rx Integrity team will investigate and report potential violations of laws, regulations or Company policy internally and suspicious orders externally to the DEA, State Boards, and other agencies as required. Rx Integrity currently owns, makes recommendations, and utilizes the Controlled Substance Order Monitoring System (CSOM) to manage the amount of controlled substance product that is shipped to the stores. The CSOM system was developed to flag orders by store by drug that are above the norm or average units of each controlled substance product that is sent to stores in a 6 week rolling period. The team reviews orders that are manipulated by the store in order to determine whether the order meets specific criteria to qualify as suspicious. Suspicious orders are sent to the DEA and State Boards as required.

The team works with various departments including Legal, Government Affairs, Logistics, Loss Prevention, IT and others to ensure company wide awareness and adhere federal/state/local laws and regulations. Rx Integrity is tasked in developing a collaborative working relationship with government, law enforcement, and industry organizations (e.g., DEA, FDA, State Boards of Pharmacy, National Retail Federation, Retail Industry Leaders Association, National Association of Drug Diversion Investigators) to drive industry leading solutions to pharmaceutical diversion.

"Walgreens has identified the following orders of interest that appear to be of an unusual size, unusual frequency or deviate substantially from a normal pattern."

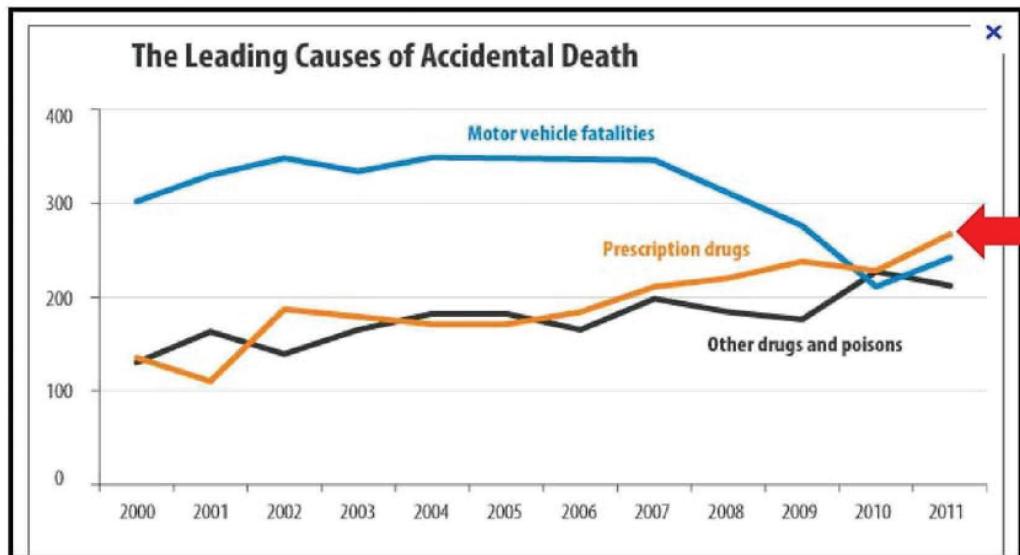
A National Prescription Drug Epidemic

- The issue of drug diversion and abuse has drawn the attention of public health officials, regulatory agencies, and public policy makers on state and national levels
- Dramatic increases in the use of and addiction to controlled substance pharmaceuticals have been seen for two decades
- Prescription drug abuse increases traffic accidents, crime, overdoses, and death
- The DEA is increasing its focus on drug wholesalers and pharmacies, in attempt to battle what the Centers for Disease Control and Prevention calls a prescription drug abuse epidemic



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Leading Cause of Death - Prescription Drugs



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This particular statistic came out of California, but there were multiple examples across the country where the leading cause of accidental death is prescription pain medications (opioid use). This national problem has brought increased scrutiny to physicians, pharmacists and drugs wholesalers from regulators, policy makers and law enforcement.

Timeline of Events

Pre-August
2010

- Steady increase in FL pill mills
- Prescribers dispensing medications

October 2010

- Change in Florida legislation restricts prescriber dispensing to only 72 hour supply of pain medications

October 2010 -
March 2011

- Dramatic increase in the number of opioid pain medications prescriptions seen at retail stores

July 2011

- Florida law amended to prohibit practitioners from dispensing C2-3, except in very limited instances



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Timeline 2012

April 2012

- Administrative Inspection Warrants were served on 6 stores and the Jupiter DC

May – June 2012

- 8 stores voluntarily removed all C-II products, Xanax & Soma
- Re-launch of Good Faith Dispensing Policy

September 2012

- ISO was issued for the Jupiter DC

November 2012

- Order to Show Cause issued to 3 of the original Florida pharmacies



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Redacted – Attorney Client Privileged and Attorney Work Product

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Target Drug GFD Checklist

National Target Drug Good Faith Dispensing Checklist			
Patient Name: _____ Rx #: _____ Date: _____			
Please select drug & provide strength (tablets/capsules only): Oxycodone _____ Hydromorphone _____ Methadone _____ Other (optional - district specific) _____			
Check boxes that apply to determine if the prescription can be filled. Attach checklist to hard copy of Rx.			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Mandatory Checklist Requirements: Must be Yes to fill prescription. 1 <input type="checkbox"/> <input type="checkbox"/> Valid government photo ID copied and attached to hard copy. For eRx, attach copy at pick-up. 2 <input type="checkbox"/> <input type="checkbox"/> No GFD refusal for this particular prescription in patient comments on IC+ profile. 3 <input type="checkbox"/> <input type="checkbox"/> If available in your state, PDMP has been reviewed, printed and attached to hard copy.		<small>RPh/Tech Initials</small>
Additional Checklist Requirements: every "no" is a red flag. Use your professional judgment to assess the prescription.			
4 <input type="checkbox"/> <input type="checkbox"/> Patient has received this prescription from Walgreens before. 5 <input type="checkbox"/> <input type="checkbox"/> This prescription is from the same prescriber for the same medication as the previous fill. 6 <input type="checkbox"/> <input type="checkbox"/> Patient and/or prescriber address is within geographical proximity to pharmacy; variances can be explained. 7 <input type="checkbox"/> <input type="checkbox"/> Prescription is being filled on time. 8 <input type="checkbox"/> <input type="checkbox"/> 3rd Party Insurance is billed (cash or a cash discount card is a red flag). 9 <input type="checkbox"/> <input type="checkbox"/> Quantity is 120 units or less, or 60 units or less if paid by cash or cash discount card. 10 <input type="checkbox"/> <input type="checkbox"/> Patient has been on this same medication strength and dose for less than 6 months.			
If in your professional judgement a call to the prescriber is warranted, review step 11. If no call is required, complete this form with your signature.			
11 <input type="checkbox"/> <input type="checkbox"/>	Call to Prescriber To begin the conversation with the prescriber, verify/confirm any number of the following points (document in notes section): *Prescription is written within prescriber's scope of practice *Diagnosis *Therapeutic regimen is within standard of care *Expected length of treatment *Date of last physical and pain assessment *Use of alternative/lesser prescription medications for pain control *Coordination with other clinicians involved in patient care For Hospice and Oncology patients only: If unable to reach the prescriber, RPh may fill the Rx without verification by the prescriber provided the elements of Good Faith Dispensing are met.		
I attest that I have used the Good Faith Dispensing Checklist validation procedures and my professional judgement to review this prescription and I have: <input type="checkbox"/> Dispensed: _____ Product review Pharmacist signature _____ <input type="checkbox"/> Refused: _____ Pharmacist signature _____ <small>(RPh must fax a copy of the refused Rx Hard Copy to DEA, FL use webform)</small>			
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The checklist is an internal document and cannot be given to anyone outside of the company.

Prescriber call is up to the pharmacist's discretion

There are NO quantity limitations – yes, higher quantities do create increased scrutiny, but the policy does not prohibit filling a large quantity prescription

The checklist will never tell the RPh should fill a prescription, but it will give the pharmacist comfort that they made the right decision if they don't fill the prescription

Pharmacists want black and white, we can't give them that. Mistakes will be made, we will fill for patients we should and will deny for patients we shouldn't deny. The checklist is merely a tool to help make those decisions easier.

Positive Feedback From Our Pharmacists

- Policy creates consistency
- Policy increases awareness for pharmacists and techs
- Pharmacists are finding that some prescribers never even check the State PMP before prescribing prescriptions
- Checklist is a useful tool for pharmacists



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We have heard a lot of positive feedback. The pharmacists appreciate the support, it has helped with consistency across all of our stores and helped increase awareness. Where we need to put forth some additional effort is to our technicians. They are on the front line and we are hearing that some feel they are getting the brunt of the new policy without fully understanding the 'why'.

We took feedback from the pilot area and made some changes to the policy. The two overwhelming pieces of feedback we received was they loved the checklist, but the phone calls were a lot of work. So, the most significant change we made is that the phone call to the prescriber is not required. It is up to the pharmacists professional judgment whether they need to call to resolve the red flags they found in processing/filling the prescription.

Walgreens is Making a Difference



**ATTORNEY GENERAL
PAM BONDI**
FLORIDA OFFICE OF THE ATTORNEY GENERAL

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Attorney General Pam Bondi News Release

April 15, 2013
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Lake Mary "Pill Mill" Doctor Sentenced to 25 Years in Prison and \$500,000 Fine

TALLAHASSEE, Fla.—After a successful prosecution by Attorney General Pam Bondi's Office of Statewide Prosecution, Judge Marlene Alva today sentenced Dr. Ronald Lynch, a "pill mill" doctor, to 25 years in prison on drug trafficking charges and a \$500,000 fine. Acting on information provided by Walgreens Pharmacy, the Seminole County Sheriff's Office, the Attorney General's Medicaid Fraud Control Unit, and the Florida Department of Law Enforcement investigated Lynch, of Integrative Medicine of Lake Mary, for illegally prescribing opiates. Lynch was found guilty on charges of trafficking in oxycodone of 4 grams or more, trafficking in oxycodone of 28 grams or more, and trafficking in morphine of 28 grams or more, all first-degree felonies.

This pill mill doctor is no longer funneling prescription drugs into our communities thanks to a great collaborative effort, beginning with Walgreens Pharmacy reporting prescriptions using a revoked Drug Enforcement Administration number," stated Attorney General Pam Bondi. "I thank the Seminole County Sheriff's Office, the Florida Department of Law Enforcement, and State Attorney Archer's office for their partnership on this case."

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We are making a difference. This is an example out of FL where our information to the DEA led to the arrest and conviction of a prescriber that was diverting drugs through his "pill mill" he received 25 years in prison.

We are seeing other chains do similar things and we are seeing wholesalers limit other pharmacies on the amount of product they are receiving. This is an industry wide problem and we are at the front, leading this change. We thank you for your commitment, what we are doing is important and you are making a difference.

Next Steps For Target Drug GFD

- Updated FAQs were launched after policy based on field questions and feedback
- Division Focus Groups
- Target Drug GFD Champions



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We know that this policy is not final, we are going to have to make tweaks and changes. Focus group calls were done over the last couple weeks and we will be making some changes based on some ideas we have received. Watch for updated information.

GFD of Pseudoephedrine

- Along with all controlled substances, PSE is included in RX Integrity oversight and monitoring
- Good Citizenship Policy – on Store Net
 - we all have a responsibility to stop the spread of illicit drug use
 - do not sell if suspicious behavior is noticed



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Ordering OTC Pseudoephedrine

- HSRX locations are not subscribed to the BDM Planogram.
 - The BDM Planogram allows items in the Daily living section to automatically re-order.
 - Due to space restrictions the HSRX sites are not able to stock all of these items and therefore have been removed from the BDM Planogram.
- Products containing Pseudoephedrine should be manually ordered flowing these guidelines.
 - Only order once a week and only order up to the highest sale week over the last 13 weeks.
 - Do not use the Telxon to place the order, all order must be place using the AS/400 Terminal.
 - Orders placed using the Telxon could result in the order being flagged and held for review by the Rx Integrity team further delaying when the product will arrive.

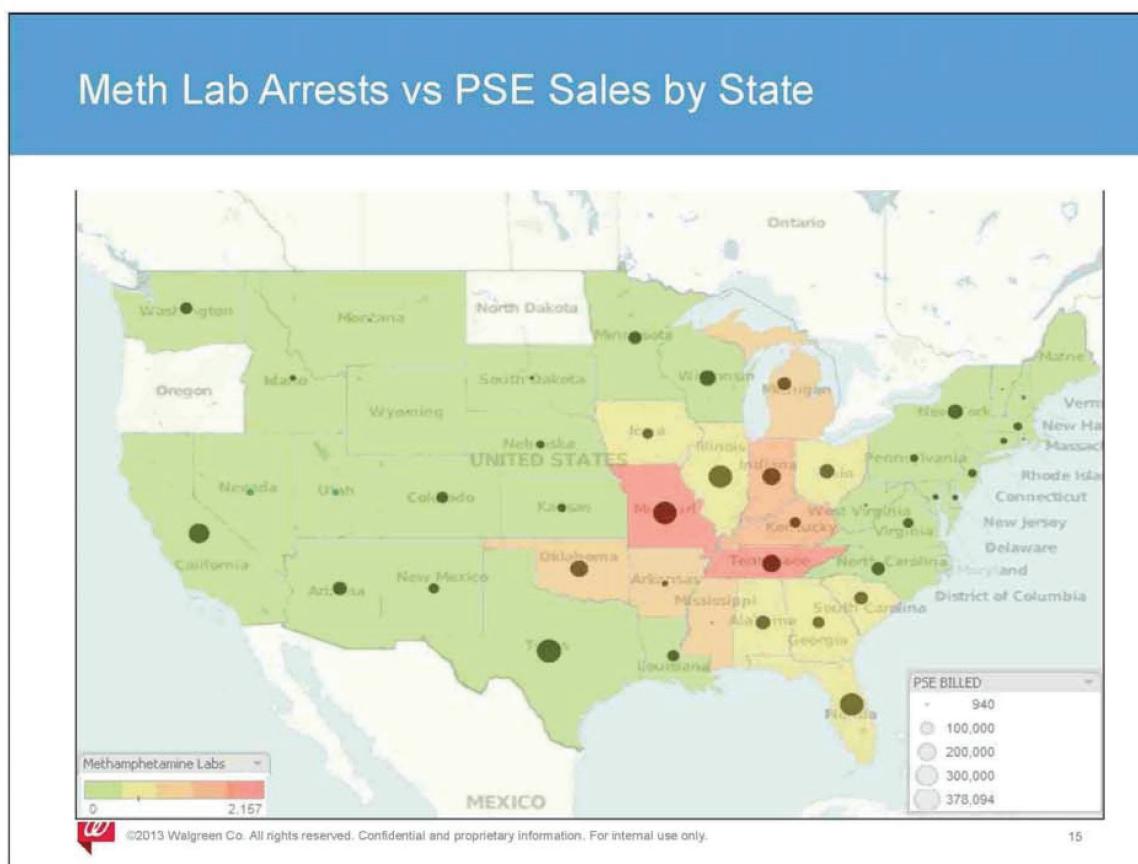


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PSE sales has the attention at the highest levels of our company. This is NOT about sales, this is about protecting our company. [REDACTED]

[REDACTED] We need to do the right thing and make sure we are following the Good Citizenship Policy and selling to those folks that do not exhibit suspicious behavior.



This map shows the relationship of Meth Lab busts in comparison to the sales in each state. Red states have the most busts and the bigger the dot the more sales in that state.

Pseudoephedrine

What can management do?

- Do not manually try to order in extra PSE product
- Allow the system to generate all orders
- Communicate to all employees: Manual orders on PSE products will result in order being cut to zero and an 'order of interest' that has to be investigated by the Rx Integrity team
- Store employees need to be aware of unusual sales of PSE products
 - example: counties around you now require a prescription, now your sales for PSE go through the roof → ask yourself why?



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What can you do? Get the message out to all employees to stop adjusting the orders or trying to bypass the system to get PSE into your store. If you are not adjusting your order and you have sales of the product, SIMS should reorder for you, if you are not getting product, open a ticket or contact RxInventory or RxIntegrity for us to investigate.

What Can Leadership Do?

- Keep the Focus on Good Faith Dispensing as a whole
- Target Drug GFD is only a portion of overall GFD
- Pharmacists are getting hung up on ICD-9 code and diagnosis, this is just one piece of the information they may need in order to satisfy their corresponding responsibility
- Any prescription that passes GFD per the Pharmacist's professional judgment may be filled, regardless of quantity



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Good Faith Dispensing is all controlled substances, we cannot lose sight of the total GFD policy because we have heightened awareness around the Target Drugs.

We must find the balance and we know this will take time, this is difficult and not black and white. Keep in mind that the prescriber conversation pieces are a guide and meant to aid the pharmacist in resolving the red flags. They only need to ask what they feel is necessary and what pertains to that prescription. We are not mandating each prescription have a diagnosis or ICD-9 code. However, we support the pharmacist if they feel they need that information to satisfy their corresponding responsibility.

It's a Rough Road, but we are making a difference!



Thank you for all you are doing to support our Good Faith Dispensing Efforts!



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